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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,849	12/14/2001	Jason P. McDevitt	03768/09630	7436

7590 10/19/2004

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EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,849

Applicant(s)

MCDEVITT ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-29 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-29 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/04 has been entered.

Claims 1-5, 10-29 and 32 are pending.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5, 15, 16, 18-21, 23-25, 27-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6, 156, 334 ("Meyer-Ingold et al.") in view of WO 97/07273 ("Ninagawa").

As regards claims 1, 2, 19, 24 and 25 and Meyer-Ingold et al. substantially disclose the instant invention. Meyer-Ingold et al. disclose wound coverings for removal of interfering factors from wound fluid. The invention is achieved by covalently bonding substances (enzymes, proteins, etc. (col. 2, lines 51-60)) that interact (*i.e.*, remove or eliminate) with interfering factors (proteases) present in wound exudates to a carrier material. Meyer-Ingold et al. further disclose the use of growth factors in combination with the interfering factors in order to improve the healing process of chronic wounds (col. 3, lines 26-34). Specifically, Meyer-Ingold et al. disclose that wound dressings (*e.g.*, dressing gauze, bandages, compresses, cotton-wool, patches, foil, *etc.*) known in the prior art can be modified by covalently bonding the trapper molecules thereto and simultaneously applying wound healing promoting substances such as protein containing growth factors (col. 5, line 1-col. 10, line 4) in the wound.

As to the method, although the steps are not explicitly stated, the process of making the disclosed wound dressing and then applying the wound dressing to a user

reads on the steps of the instant invention. Moreover, the "trapper molecules" are **capable** of withdrawing, entrapping and removing a protease from the wound site.

Meyer-Ingold et al. fail to teach that the carrier material (wound dressing) consists essentially of protein fibers. However, Ninagawa discloses the use of surgical gauze prepared from short silk fibers.

It would have been obvious to one having ordinary skill in the art to select the surgical gauze of Ninagawa, which consists of silk (protein) fibers, as the carrier material since Meyer-Ingold et al. disclose that wound coverings known in the prior art can be modified and used in the invention.

Additionally, the specific step of "selecting" is inherently accomplished when the silk surgical gauze is used.

As regards claims 4, 5, 27 and 28, the fibers are in the form of a silk fabric (gauze).

As regards claims 15 and 20, Meyer-Ingold et al. disclose at col. 9, line 65-col. 10, line 4 that the wound healing substances, such as for example, growth factors can be applied into the wound, thereby being separate from the wound dressing.

As regards claims 16 and 21, Meyer-Ingold et al. fail to disclose that the growth factor is in form of an ointment, lotion, solution or gel. Absent a critical teaching and/or a showing of unexpected results derived from the use of a growth factor in the form of an ointment, lotion, solution or gel, the examiner contends that the form of the growth factor is an obvious design choice, which does not patentably distinguish applicant's invention.

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As regards claims 18, 23 and 32, note col. 10, lines 1-2, which discloses the use of PDGF (platelet derived growth factor).

As regards claim 29, Meyer-Ingold discloses that the wound dressing further comprises a non-protein-containing component in addition to the protein-containing component (col. 8, line 1-col. 10, line 6).

Claims 1, 3, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Ingold et al. in view of U.S. Patent No. 5,447,505 ("Valentine").

As regards claims 1, 3, 24 and 26, Meyer-Ingold et al. substantially disclose the instant invention. Meyer-Ingold et al. disclose wound coverings for removal of interfering factors from wound fluid. The invention is achieved by covalently bonding substances (enzymes, proteins, etc. (col. 2, lines 51-60)) that interact (*i.e.*, remove or eliminate) with interfering factors (proteases) present in wound exudates to a carrier material. Meyer-Ingold et al. further disclose the use of growth factors in combination with the interfering factors in order to improve the healing process of chronic wounds (col. 3, lines 26-34). Specifically, Meyer-Ingold et al. disclose that wound dressings (*e.g.*, dressing gauze, bandages, compresses, cotton-wool, patches, foil, *etc.*) known in the prior art can be modified by covalently bonding the trapper molecules thereto and simultaneously applying wound healing promoting substances such as growth factors (col. 9, line 57-col. 10, line 4) in the wound. Moreover, the "trapper molecules" are **capable** of withdrawing, entrapping and removing a protease from the wound site.

As to the method, although the steps are not explicitly stated, the process of making the disclosed wound dressing and then applying the wound dressing to a user reads on the steps of the instant invention.

Meyer-Ingold et al. fail to teach that the carrier material (wound dressing) consists essentially of protein fibers. However, Valentine discloses the use of wool, gauze, unmedicated cotton, *etc.* (col. 1, lines 9-15) as being a material used to treat wounds, thereby being a dressing.

It would have been obvious to one having ordinary skill in the art to select the wound treatment material of Valentine, which consists of wool (protein) fibers, as the carrier material for since Meyer-Ingold et al. disclose that wound coverings known in the prior art can be modified and used in the invention.

Additionally, the specific step of "selecting" is inherently accomplished when the cotton-wool or the wool gauze is used.

Claims 1, 10-14, 17, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication 2002/0064551 ("Edwards et al.") in view of Ninagawa and U.S. Patent No. 5,158,555 ("Porzilli").

As regards claims 1, 19 and 22 Edwards et al. disclose a method for sequestering or inhibiting protease at a wound site that substantially reads on the claimed invention. Edwards et al. specifically, disclose wound dressings of the formula x-a (x bonded to a), wherein x and a are selected from a long list of materials. Included in the list of materials are cotton cellulose formed as woven or nonwoven gauze and

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proteins (para. 44), which are capable of removing a protease from a wound site once applied (abstract, paragraph 31, and page 3).

Edwards et al. fail to teach the step of selecting fibers that consist essentially of protein fibers and forming a wound dressing from the fibers. However, Ninagawa discloses the use fibers, which consist of silk protein, in making surgical gauze.

In view of Ninagawa, it would have been obvious to one having ordinary skill in the art to modify Edwards et al. by using silk gauze as the carrier material because it is soft and does not damage internal tissues.

Edwards et al. also fail to teach selecting at least one protein from the group consisting of growth factors, cytokines, and chemokines for application to the wound site. However, Porzilli discloses a wound dressing comprising a protein fibers and an epidermal growth factor (inherently a protein) in order to heal a wound quickly.

In view of Porzilli, it would have been obvious to one having ordinary skill in the art to modify the method disclosed in Edwards et al. with the additional step of adding a protein containing growth factor to the wound dressing in order to heal a wound quickly.

As to step d), applying the wound dressing and protein to the wound site so that the fibers are in contact with the wound site, the applicant should note that Edwards et al. disclose applying the carrier material with the interfering factors on a wound. The examiner contends that the application of the carrier material with the interfering factors on the wound intrinsically accomplishes applicants' step d).

As regards claims 10-14, since the applicants disclose wound dressings consisting essentially of the same material (e.g., silk protein), the modified wound

dressings of Edwards et al. is also capable of removing proteases which comprises elastase, neutrophil elastase, gelatinase, gelatinase B (MMMP-9) and plasmin, since the applicants have not chemically or physically altered the protein fibrous material in any manner distinguishing it over silk fiber dressings of Ninagawa.

As to the claim 17, a, which is bonded to the carrier material (dressing) is capable of being a protein (para. 44).

Response to Arguments

In response to applicants' argument regarding the conjunction of Ninagawa with Meyer-Ingold, et al., the examiner contends that the motivation to select a silk dressing comes directly from the disclosure of Meyer-Ingold, et al., which states that wound dressings (e.g., dressing gauze, bandages, compresses, cotton-wool, patches, foil, etc.) known in the prior art can be modified (col. 5, line 1- col. 10, line 4). In light of this disclosure, it would have been obvious to one having ordinary skill in the art to select the known silk prior art dressing for modification and use. Moreover, even if the Meyer-Ingold et al. did not recognize the benefits obtained by the claimed invention, the disclosure of the use of well known prior art dressings for modification and use accomplishes applicant's invention.

In response to applicants' arguments regarding Edwards et al., the examiner cannot locate a 37 C. F. R. 1.131 affidavit or declaration in the file proving that the conception of applicants' invention was before the earliest claimed priority date of Edwards et al. Applicant is invited to resubmit the affidavit or declaration.

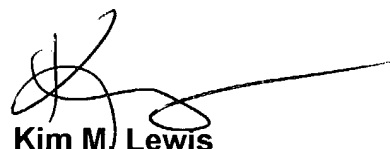
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In response to applicants' arguments regarding the combination of Meyer-Ingold, et al. and Valentine, et al., note the remarks above regarding Meyer-Ingold, et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
October 16, 2004